Remarks/Arguments:

This is a Request for Continued Examination under 37 CFR 1.1114.

In response to the Office Action dated August 10, 2004, the applicants provide the above amendment in conjunction with these remarks. Reconsideration and withdrawal of the rejections under 35 U.S.C. §§ 101 and 112 are respectfully requested in light thereof.

A. Amendments to the claims

Claims 1-8 and 15-29 have now been canceled without prejudice to applicants' right to pursue the subject matter of these claims in a separate divisional application. New claims 40-42 have been added to more distinctly claim the disclosed invention. Support for these claims may be found in the Specification at paragraphs [0025], [0031], [0032], [0052], [0054], [0055], Figures 19 and 20, and original claims 1, 4, 7, 8, and 19. It is submitted that no new matter is introduced by these amendments and new claims.

B. Claim rejections under 35 U.S.C. § 101

Claims 30-34 were rejected because it was asserted that the claimed invention is not supported by a specific, substantial, or well-established utility. It was pointed out that some uses disclosed for the claimed DNA sequence are not specific to the claimed sequence, but are generally applicable to any nucleic acid, and that no substantial utility has been asserted. There was no assertion that the asserted utilities for the invention were not credible.

Applicants traverse the rejection and submit that the invention as recited does have patentable utility. Claim 42 has been added to specifically address the utility of the claimed sequence.

As the Applicants pointed out in their Amendment of August 22, 2003, the claimed sequence can specifically be used to modulate winter dormancy in plants. Specification paragraphs [0052]-[0053], and Example 8. The specific use of modulating winter dormancy in plants is **not** generally applicable to any nucleic acid.

Chart 2 of the Background section of the specification lists several specific genes and proteins that have been implicated in the dormancy phenomenon in a variety of plant species. This list includes the phosphorylase enzyme in duckweed plant, and β- and α- amylase enzymes in aquatic and grain plants respectively. These are specific enzymes that have been uniquely associated with winter dormancy in select plant species. These examples illustrate that

dormancy related genes and proteins may vary among different plant species, but are specific in function, and the relation of their DNA to winter dormancy is not a generalized relationship applicable to "any nucleic acid."

In contrast, the Office Action provides no evidence that nucleic acids in general can modulate winter dormancy in plants. Without evidence to the contrary, the Applicants have established that the claimed invention has a highly specific utility in modulating winter dormancy in plants.

Although the specification may list other uses for the claimed DNA sequence which are nonspecific, only one specific, substantial, or well-established utility is required in order to meet the requirements of 35 U.S.C. § 101. "[A]dditional statements of utility, even if not 'credible,' do not render the claimed invention lacking in utility." MPEP 2107.02I. *See also, Raytheon v. Roper,* 724 F.2d 951, 958 (Fed. Cir. 1983) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. 101 is clearly shown.")

Modulation of winter dormancy in plants is also a substantial utility. Winter dormancy is a well-known phenomenon in plants. See Specification paragraph [0008]. Reduced dormancy periods, as well as extended dormancy periods can have severe agricultural and economic ramifications. See Specification, paragraphs [0010]-[0011]. The Specification also establishes that the "[m]odulation of dormancy has been and will continue to be a key issue in agriculture system[s]." Specification paragraph [0010]. This statement is supported by citation of a number of studies conducted on dormancy in various plant species. See paragraphs [0007], [0008], [0015], and Chart 2. In the tea industry, in particular, a reduced period of dormancy is required in regions with low temperatures and short day length. Specification paragraph [0011]. A number of methods to suppress or prolong the dormancy period in plants have been developed. These include regulating environmental temperature and light levels for greenhouse or incubator grown plants; spraying with chemicals such as cyanide; treating with plant hormones such as giberellic acid; and transforming plants with bacterial enzymes that inhibit sprouting, such as ADP glucose phosphorylase. Specification paragraph [0015]. Thus, the claimed DNA sequence may not be the sole means to regulate winter dormancy in plants, but it is nevertheless a substantial use for the claimed sequence. The invention could have a tremendous impact on food supplies, in particular tea, which is consumed by over two-thirds of the world's population. See Recent Advances of Tea (*Camellia sinensis*) Biotechnology, T.K. Mondal, *et al.*, Plant Cell, Tissue and Organ Culture 76: 195-254, 2004. An abstract of this article is enclosed for the Examiner's convenience.

"An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention ... and (ii) the utility is specific, substantial, and credible. If an invention has a well-established utility, rejections under 35 U.S.C. § 101 and 35 U.S.C § 112, first paragraph, based on lack of utility should not be imposed." MPEP 2107.02(B)(II). Based on the art cited in specification and on the Mondal paper cited above, it is apparent that those of skill in the art would immediately appreciate the usefulness of an invention that can regulate winter dormancy in tea and other plants.

Differential gene expression is the primary means through which plant and animal growth and development are regulated. See Molecular Biology of the Cell, B. Alberts, *et al.*, Garland Publ. Inc., N.Y., 1983, p. 26. Differential gene expression studies have been used to discover many genes that regulate stress tolerance in plants. For example, pyrroline-5-carboxylase is over-expressed in response to water stress (Kishor *et al.*, Plant Physiol. 108: 1387-1394, 1995), and chloroplast superoxide dismutase is over-expressed under a variety of stress conditions in plants (Sengupta *et al.*, P.N.A.S. (U.S.A.) 90: 1629-1633, 1993). Stress responses can be deliberately regulated through over-expression of transgenes in transformed plants. For example, Kasuga et al. have shown that transformation and over-expression of a stress-inducible gene in *Arabidopsis* improved tolerance to a variety of stresses. (Nature Biotechnology 17: 287-291, 1999).

Accordingly, one of skill in the art would immediately recognize that a gene whose expression is stimulated in non-dormant plants or plants in which dormancy has been terminated and meristematic growth has resumed will play an important role in the regulation of dormancy. As shown in Figures 19 and 20 of the Specification, the transcript encoded by the claimed sequence is expressed in great abundance in non-dormant plants and in plants in which dormancy has been terminated by application of giberellic acid, but is barely detectable in dormant plants. While the claimed sequence may not be the only gene expressed in response to giberellic acid treatment, the claimed sequence is clearly associated with the regulation of meristematic growth in the apical buds of the tea plant and can be used to regulate dormancy. Therefore, applicants respectfully request that the rejections under 35 U.S.C. §101 be withdrawn.

If the Office believes that the utility asserted by the Applicants is not specific, substantial and credible, or well-established, applicants invite the Office to provide evidence to the contrary. (See, for example, 37 C.F.R. § 1.104(d)(2); MPEP 2144.03).

C. Rejections under 35 U.S.C. § 112

Claims 30-34 stand rejected under 35 U.S.C. § 112 first paragraph for not being sufficiently described or enabled by the Specification. The Office alleges that applicants failed to respond to the enablement rejection in their June 3, 2004 Amendment. However, applicants noted in this Amendment that their response to the enablement rejection was incorporated in their response to the utility rejection. As cited above, an enablement rejection based on lack of utility should not be imposed if a well-established utility is asserted. Applicants traverse the rejection and again incorporate the above arguments related to utility in their response to the rejection under 35 U.S.C. § 112, first paragraph.

The written description requirement may be met for a polynucleotide by listing the sequence of the claimed polynucleotide. MPEP 2163(II)(A)(3)(a); *Regents of Univ. Cal. v. Lilly*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). As the Applicants have listed Seq. ID NO: 1 in accordance with the requirements of the U.S.P.T.O., the written description requirement for the claimed polynucleotide has been met.

As to enablement, the Specification states in paragraphs [0052], and 0053] that the claimed sequence can be used to regulate winter dormancy in plants by transforming plants with the sequence either through *Agrobacterium* or biolistic (gene gun) transformation. Biolistic is misspelled in the Specification and the Applicants apologize for any confusion this may have caused. Both of these methods are well-known and widely practiced by those of skill in the art. For example, "Gene Transfer and Expression in Plants," in Methods in Molecular Biology, (Clifton, N.J., 2004), presents an overview of methods for *Agrobacterium*-mediated and biolistic transformation in plants. Furthermore, the tea plant has been successfully transformed with *Agrobacterium*, and plants have been regenerated from the transformants. See "Transgenic tea plants obtained by *Agrobacterium*-mediated transformation of somatic embryos," T.K. Mondal, *et al.*, Plant Cell. Rep. 20: 712-720, 2001, a copy of which is enclosed for the Examiner's convenience. Thus, the methods necessary to transform plants with the claimed sequence are well-known in the art and the use of the claimed invention is enabled. The methods require some routine experimentation, but routine experimentation known to those of skill in the art is not undue experimentation. See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) ("[A] considerable amount of experimentation is permissible, if it is merely routine ...)".

In view of the above remarks, the Applicants respectfully request that the rejections under §112, first paragraph for failure of enablement and written description be withdrawn.

D. Extension of Time

Authorization for payment via credit card for a three-month extension of time accompanies this response. Pursuant to 37 C.F.R. § 1.136(a)(3), the Commissioner is requested to treat this Authorization as a constructive Petition for an Extension of Time.

E. Conclusion

It is respectfully submitted that the claims are in condition for immediate allowance and a notice to this effect is earnestly solicited. The Examiner is invited to phone applicants' attorney if it is believed that a telephonic or personal interview would expedite prosecution of the application.

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The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

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Kathy Spina

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